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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,632	02/19/2002	Paul Habermann	DEAV2001-0008 US NP	2603
5487	7590	12/08/2009		
ANDREA Q. RYAN SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 12/08/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No. 10/076,632	Applicant(s) HABERMANN, PAUL	
	Examiner David J. Steadman	Art Unit 1656	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 November 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): see Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: 22-24 and 30-35.
 Claim(s) rejected: 1,7-14,21 and 25-28.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/David J. Steadman/
 Primary Examiner, Art Unit 1656

Continuation of 11. does NOT place the application in condition for allowance because:

Claim Objection

The objection to claim 1 in the recitation of "...sequence coding hirudin..." is maintained and, as noted in the prior Office action, in order to improve claim form, it is suggested that the noted phrase be amended to recite, e.g., "...sequence encoding hirudin..." Although applicant argues the claim has been amended according to the examiner's suggestion, it is noted that the term "coding" has not been replaced with "encoding".

The objection to claim 1 in the use of the designation "AsmR" (using lowercase "s"); the objection to claim 1 in the recitation of "n=O" and "m=O" (using the letter "O"); the objection to claims 14, 25, and 27 in the recitation of "production of fusion protein"; the objection to claims 30-35 are objected to in the recitation of "A process" or "A nucleic acid"; and the objection to claim 33 in the recitation of "(Gly-Asn-Ser-Ala-Arg)" are withdrawn in view of the instant claim amendment.

In view of applicant's instant amendment to claim 1, claim 34 is an improper dependent claim because it does not further limit claim 33.

Claims 22-24 and 30-35 are objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 33-35 under 35 U.S.C. 112, second paragraph, as being unclear in the scope of "Hir" is withdrawn in view of the instant amendment to claim 1 to define "Hir" as "hirudin or lepirudin", where "lepirudin" is recognized in the prior art as hirudin with an additional N-terminal leucine.

Claim Rejections – Double Patenting

The provisional rejection of claims 1 and 7-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-12, and 38 of co-pending application 10/076,631 is maintained for the reasons of record and the reasons set forth below. The provisional rejection was fully explained in a prior Office action. See, e.g., item 19 at p. 12 of the Office action mailed on 12/12/08. Applicant does not address the provisional rejection and it is noted that the 10/076,631 application has passed to issue.

The rejection of claims 1, 9, 12-14, 21, and 25-28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5, 8, and 10-18 of US Patent 7,202,059 in view of Dörschug et al. and Schmid et al. is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See, e.g., item 20 beginning at p. 12 of the Office action mailed on 12/12/08. Applicant argues the rejection is obviated by filing a terminal disclaimer (hereafter "TD"). The examiner acknowledges the filing of a TD on 11/10/09, however, this filing fails to obviate the rejection because the TD is defective as follows. 1) The TD does not contain the phrase "run with any patent granted". 2) The TD is self contradictory. It refers to Sanofi-aventis as "the whole and entire right, title and interest of United States Patent Application Serial No. 10/076,632" via assignment from the "inventor," while its caption reflects the presence of inventors (where "the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made" would be the correct statement). The original declaration only recites one inventor. 3) The TD states that "Applicants hereby disclaim" rather than the required "The owner of the present application" (or similar language). 4) The reference patent is stated to be owned by Sanofi-aventis and Wacker-Chemie, while the target is apparently owned by Sanofi-aventis. The correct waiver of the "right to separately enforce" is stated in the TD, for a joint research agreement (JRA), however, the requirements of 37 CFR 1.71(g) are not satisfied. Specifically, the specification has not been amended in accordance with 1.71(g)(1) and there is no fee in accordance with 1.71(g)(2). If the requirements of 37 CFR 1.17(g) have not been satisfied, then 37 CFR 1.321(d) is not applicable.